Remarks

The Interview

Applicants and the undersigned greatly appreciate the opportunity to speak to the examiner and his supervisor regarding the invention and discuss proposed claim amendments. As discussed at the interview, Dr. Goldstein has been a practicing dermatologist for many years. In the course of his treatment of patients, he has observed that many mid and high potency steroids cause serious side effects including thinning of the skin, hypopigmentation, and striae distensae, which may be as significant of a problem as the presenting condition since fungal conditions take up to four weeks to respond to treatment. Indeed, the American Academy of Pediatrics states that many of these steroids, especially the high and mid-level steroidal antiinflammatories, should not be used in children due to the risk of side effects. During this extended period of treatment, the patient have to put up with irritation, redness and itching. Therefore there is a need for a composition that is both effective but safe, with minimal side effects.

Based on his extensive clinical experience, Dr. Goldstein has discovered that low and low-mid potency steroidal antiinflammatories can be combined with an antifungal to provide a safe and effective treatment with minimal side effects. He presented photos of one case study wherein the patient had presented with scaly red and inflamed, raised areas of skin infected with inflammatory tinea. This patient had previously been treated with a variety of medications, none of which were effective. Dr. Goldstein treated the patient with a topical cream containing 0.05%

desonide and 1% clotrimazole. Within a few days, the redness and swelling had disappeared, leaving skin looking almost normal in the photographs.

Rejection under 35 U.S.C.§ 112

Claim 14 was rejected under 35 U.S.C. § 112, as indefinite. This rejection is respectfully traversed if applied to the amended claim which deletes the objected to phrase.

Rejections under 35 U.S.C. §§ 102 and 103

Claims 1-10, 13-16 were rejected under 35 U.S.C. § 102 as disclosed by U. S. Patent No. 6,444,647 to Robinson, et al. Claims 1-5, 7-13 were rejected under 35 U.S.C. § 102 as disclosed by U. S. Patent No. 6,075,056 to Quigley, et al. Claims 1-9, 13, 14, 16 were rejected under 35 U.S.C. 102 as disclosed by U. S. Patent No. 5,686,089 to Mitra, et al. Claims 1-10 were rejected under 35 U.S.C. § 102 as disclosed by U. S. Patent No. 5,219,877 to Shah, et al.

Claim 15 was rejected under 35 U.S.C. § 103 (a) as obvious over U. S. Patent No. 5,686,089 to Mitra, et al.

These rejections are respectfully traversed if applied to the amended claims.

As discussed at the interview, the invention is the selection of the class of low to low mid potency steroidal antiinflammatories that can be used in combination with antifungal medication to treat a patient with efficacy but with minimal side effects. The claims have been amended as discussed at the interview to define the claimed composition and method as follows:

A topical formulation (support is found at page 2, line 7)

low or mid-potency steroidal antiinflammatories (page 2, lines 7-10; page 3, lines 19-21) (*See* attached printout from the National Psoriasis Foundation website showing the different categories and which products lie within each)

having a higher potency than 1 wt% hydrocortisone (page 5, lines 13-15)

in a concentration between 0.01 wt% and 5.0 wt% (page 4, lines 15-16)

New claim 17 has support at page 2, lines 7-10; page 3, lines 19-21.

The data presented at the interview demonstrated the unexpected efficacy and lack of side effects of one non-halogenated steroidal antiinflammatory, desonide, in combination with an antifungal. Additional data showing the same unexpected efficacy and lack of side effects for other members of the claimed class of low to low-mid potency steroidal antiinflammatories is submitted in the attached Declaration under 37 C.F.R. § 1.132 by Dr. Goldstein. Members of the claimed class that have been shown to produce results comparable to a topical cream containing 0.05% desonide and 1% clotrimazole are:

Clotrimazole 1% cream with alclometasone dipropionate 0.05% cream applied twice daily;

Oxicanozole cream 1% with Hydrocortisone cream 2½% applied twice daily;

Econazole cream 1% with fluocinalone acetonide cream 0.01% applied twice daily; and

Econazole cream 1% with alclometasone dipropionate 0.05%, applied twice daily.

U.S. Patent No. 6,075,056 to Quigley, et al. discloses the use of steroidal antiinflammatories with a wide range of potencies (*see* col. 2, lines 7-10; col 4, line 55 to col. 5,

line 51). There is no recognition that the potency of the steroidal antiinflammatory is the cause of the side effects and can be eliminated not by changing the carrier as suggested by Quigley but by selecting a narrow class of steroidal antiinflammatories.

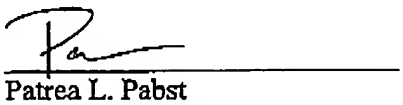
U.S. Patent No. 5,219,877 to Shah, et al. describes a gel formulation for topical administration including an imidazole antifungal in combination with a mid-potency steroidal antiinflammatory. As described at col. 4, lines 3-16, this class of compounds is not within the claimed class of low and low-mid potency steroidal antiinflammatories.

U.S. Patent No. 5,686,089 to Mitra et al. describes treatment with a topical formulation to treat infections with an antimicrobial agent (col. 3, lines 1-49) which can include an antiinflammatory (col. 6, line 65 to col. 7, line 28). There is no teaching of the claimed class of steroidal antiinflammatories, the problems with treatment with mid and high potency antiinflammatories, nor that one should select low or low-mid potency steroidal antiinflammatories.

U.S. patent No. 6,444,647 to Robinson, et al. describes a skin care composition containing as active ingredients a vitamin B3 comopund, farnesol, phytantriol or mixtures thereof, and a carrier. There is nothing teaching one to select low to low-mid potency steroidal antiinflammatories for treatment of skin conditions.

In summary, applicants have demonstrated that the claimed combination unexpectedly provides efficacy and safety, which is neither recognized by nor obvious from the prior art. Allowance of all claims as amended is therefore earnestly solicited.

Respectfully submitted,



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